IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES ATTACHED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN SUPPORT OF MOTION[1] TO EXCLUDE CERTAIN TESTIMONY OF TERESA IRWIN, M.D., PURSUANT TO FED. R. EVID. 702 AND *DAUBERT*

Plaintiffs, pursuant to Fed. R. Evid. 702 and *Daubert*,[2] submit their reply in support of Plaintiffs' motion to exclude certain opinions that Teresa Irwin, M.D., an expert for Defendants, set forth in her general expert report and in her deposition. In reply to the arguments asserted by Defendants in opposition to Plaintiffs' motion, Plaintiffs say as follows:

INTRODUCTION

Defendants argue:

1. Dr. Irwin does not offer "design" opinions;
2. Dr. Irwin opines there is no evidence connecting fraying or particle loss to complaints of pain; and
3. Dr. Irwin opines that Defendants' mesh pore size is "state of the art."

[1] In compliance with PTO No. 217, S*ee* Exhibit A for a list of cases to which this Reply applies.
[2] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

These "opinions" should be excluded because Dr. Irwin is not qualified to testify about "design" of Defendants' polypropylene mesh products, her opinions concerning "fraying and particle loss" are not reliable and her opinions related to "state of the art" constitute a legal conclusion.

ARGUMENT

I. Plaintiffs Challenged Specific Area of Dr. Irwin's Opinions That Do Not Meet *Daubert* Requirements

Plaintiffs agree that they did not challenge all of Dr. Irwin's opinions and, unlike Defendants have done on multiple occasions with experts previously approved by this Court, did not assert challenges seeking to have this Court declare that Dr. Irwin was not qualified to provide opinions that are within the scope of her education, training and experience. Plaintiffs challenged Dr. Irwin where: (1) she strays far from her field – giving opinions concerning the design of the mesh; (2) her opinions are not reliable – giving opinions on "fraying and particle loss"; or (3) her opinions constitute a legal conclusion – "state of the art." Defendants erroneously assert that Plaintiffs "concede the legitimacy of her overarching qualifications and the reliability of her methodology." While Plaintiffs quoted specific portions of Dr. Irwin's general report showing her "design" opinions, Plaintiffs challenged any and all of Dr. Irwin's opinions on design because she is not qualified to testify about design of mesh products.

II. Dr. Irwin Specifically Opines on Design Issues.

Contrary to Defendants' assertions, Plaintiffs are not categorizing Dr. Irwin's opinions as anything other than she categorized those opinions in her General Report and in the language the actual opinions. The only "fictions" are Defendants' attempts to rehabilitate those opinions and Dr. Irwin's qualifications to testify about design issues in this case.

a. Dr. Irwin "admitted" she is not qualified to testify about design.

Apparently, Defendants are abandoning the position on design qualifications that they have asserted against Plaintiffs similar experts in this litigation. In other cases, Defendants have argued that a methodology that relies on the physician's education, training, clinical experience and review of medical literature do not qualify the expert to testify about design of the mesh. This Court has ruled on several occasions that similar, if not more extensive qualifications were not sufficient to satisfy *Daubert*.

In *Tyree v. Boston Scientific Corp.*,[3] this Court determined that Dr. Jerry G. Blaivas was not qualified to testify about the design of pelvic mesh products. One of the "design" opinions held by Dr. Blaivas in *Tyree* was "[a] permanent device, such as BSC Advantage and Pinnacle, should not have been designed to be placed in a surgically contaminated field. . . ."[4] In *Huskey v. Ethicon, Inc.*[5] and *Edwards v. Ethicon, Inc.*,[6] this Court recognized his qualifications as an expert - "Dr. Blaivas is a urologist and one of the pioneers of sling surgery for women with sphincter incontinence. . . . He has extensive experience treating patients with complications related to synthetic sling surgery."[7] Despite Dr. Blaivas' "extensive experience treating patients with complications related to synthetic sling surgery," in *Tyree*, on the issue of Dr. Blaivas' design opinions, this Court determined he was not qualified. The Court ruled:

> Dr. Blaivas's experience removing SUI devices and observing complications during the removal process does not alone render him qualified to opine as to design. Dr. Blaivas worked in developing the autologous rectus fascial sling operation. However, this experience in developing procedures does not make him an expert in the design of a medical device. (See Blaivas Report [Docket 239–1], at 1–2). As a result, Dr. Blaivas lacks the "knowledge, skill, experience, training,

[3] 2104 WL 5320566 (S.D.W. Va. 2014).
[4] *Tyree*, 2104 WL 5320566 at *47.
[5] 2014 WL 3362264 (S.D.W. Va. 2014).
[6] 2014 WL 3361923 (S.D.W. Va. 2014).
[7] *Huskey*, 2014 WL 3362264 at *19; *Edwards*, 2014 WL 3361923 at *12.

> or education" as to product design that Federal Rule of Evidence 702 requires. Fed.R.Evid. 702.[8]

This Court ruled the same way based on similar qualifications of a defense expert. In *Wise v. C.R. Bard, Inc.*,[9] this Court excluded design opinions of Dr. Marshall Austin, one of Bard's experts, and concluded:

> I agree with the plaintiffs that these opinions about the Avaulta's overall design go beyond Dr. Austin's expertise. While he has studied and observed the interaction between tissue and mesh products such that he can opine about biocompatibility, he has no demonstrated experience in designing or evaluating transvaginal products.[10]

In *Wise*, the design opinions that were excluded related to "product design generally, or the Avaulta [products] specifically", "the position statement of the American Urogynecologic Society, which supports the use of mesh products to treat POP or SUI", and a conclusion "that Bard's products 'do not have inherent design defects.'"[11]

On the other hand, where an expert had specific experience in the design of mesh products, this Court has held the expert was qualified to testify about design of pelvic mesh products. In *Tyree*, the Court rejected a challenge that Dr. Ostergard was not qualified to testify about design issues and held:

> After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products.[12]

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[8] *Tyree*, 2104 WL 5320566 at *47.
[9] 2015 WL 570070 (S.D.W. Va. 2015).
[10] *Wise*, 2015 WL. 570070 at *4.
[11] *Id.*
[12] *Tyree*, 2104 WL 5320566 at *36; *see also Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *7 (S.D.W. Va. 2015)(finding Dr. Ostergard was qualified to testify about design issues).

Defendants' arguments that Dr. Irwin's clinical experience and review of literature constitutes "research" into design issues is without merit. This is the same methodology that this Court refused to accept for Dr. Blaivas and Dr. Austin. Defendant's assertion that Plaintiffs' counsel defined the term "research" to exclude clinical experience and literature review is absolutely correct because neither qualifies Dr. Irwin to testify about design issues. When limited to her actual "design" experience, Dr. Irwin admitted she had none over and over again. Dr. Irwin admitted that she:

- Never designed a pelvic mesh or consulted with a mesh manufacturer regarding the design of a pelvic mesh;[13]
- Never looked at the "specifics of the design of a pelvic mesh to determine, you know, okay, we need to do this with it, it needs to have this many – this is how it needs to be knitted, this is what it need to be made of, this is --;[14]
- Never published an article concerning design of pelvic mesh;[15]
- Does not have a background in pore size, never consulted with a mesh manufacturer regarding pore size, never published articles concerning pore size or never done any independent research on pore size;[16]
- Does not have a background in weave of pelvic mesh, never consulted with a mesh manufacturer regarding weave of pelvic mesh, never published articles concerning weave of pelvic mesh or never done any independent research on weave of pelvic mesh;[17]
- Does not have a background in weight/density of pelvic mesh, never consulted with a mesh manufacturer regarding weight/density of pelvic mesh, never published articles concerning weight/density of pelvic mesh or never done any independent research on weight/density of pelvic mesh;[18]
- Does not have a background in absorption of pelvic mesh, never consulted with a mesh manufacturer regarding absorption of pelvic mesh, never published articles concerning absorption of pelvic mesh or never done any independent research on absorption of pelvic mesh;[19]
- Does not have a degree in biocompatibility of pelvic mesh, never consulted with a mesh manufacturer regarding biocompatibility of pelvic mesh, never

[13] *See* Ex. C to Plaintiffs' Memorandum (Doc. No. 2006-3) at 35:20 – 36:2.
[14] Ex. C (Doc. No. 2006-3) at 36:21 – 37:4.
[15] Ex. C (Doc. No. 2006-3) at 37:5-8.
[16] Ex. C (Doc. No. 2006-3) at 37:18 – 38:11, 38:19-22.
[17] Ex. C (Doc. No. 2006-3) at 39:11 – 40:2.
[18] Ex. C (Doc. No. 2006-3) at 40:15 – 41:8.
[19] Ex. C (Doc. No. 2006-3) at 42:1 – 43:2.

published articles concerning biocompatibility of pelvic mesh or never done any independent research on biocompatibility of pelvic mesh;[20] and

- Never tested pelvic mesh materials concerning biomaterial issues outside her clinic practice, never consulted with a mesh manufacturer regarding biomaterial issues of pelvic mesh, never published articles concerning biomaterial issues of pelvic mesh or never done any independent research on biomaterial issues of pelvic mesh;[21]

While Dr. Irwin's clinical experience and literature review may qualify her to testify about some issues in her general report and case specific reports, she is not qualified to testify about design issues relating to the TVT mesh.

b. Dr. Irwin opines on specific design issues of the TVT mesh.

Defendants complain that Plaintiffs "cobble[d] together a series of non-consecutive pararaphs" of Dr. Irwin's General Report to argue she is offering design opinions. Plaintiffs specifically identified portions of Dr. Irwin's report that consist of design opinions she is not qualified to offer. Dr. Irwin's design opinions are similar to the design opinions of Dr. Blaivas, i.e, "A permanent device, such as BSC Advantage and Pinnacle, should not have been designed to be placed in a surgically contaminated field. . . ."[22] All of the following opinions specifically relate to the design of the TVT mesh.

- For synthetic mesh, pore size (space between fibrils); weave (mono vs. multifilament); weight (or the density); and absorption (absorbable vs non absorbable) are the critical factors of the graft material.[23]
- In synthetic material, pore size and weave influences cellular infiltration, risk of infection, mesh density and flexibility. . . .[24]
- Weight and elasticity are determined by pore size. Meshes with larger pores tend to be of a smaller weight and more elastic, versus the smaller-pored meshes which are of larger weight and less elastic. . . . There is a need for an optimal weight/density, such that if it is too light, then there is a loss in the efficacy of its intended function. Treating an anatomical problem versus a functional problem requires different specifications, as in the case of treating

[20] Ex. C (Doc. No. 2006-3) at 43:14 – 44:12.
[21] Ex. C (Doc. No. 2006-3) at 44:23 – 45:17.
[22] *Tyree*, 2104 WL 5320566 at *47.
[23] *See* Ex. B to Plaintiffs' Memorandum (Doc. No. 2006-2) at p. 25.
[24] Ex. B (Doc. No. 2006-2) at p. 25.

prolapse versus incontinence. An ultra- lightweight mesh may work well to improve the anatomic defect of prolapse, but would not accomplish improvement in the functional defect of incontinence. The latter is best accomplished by a lightweight mesh like the TVT mesh.[25]

- If there are only 3 pores across, this is probably not enough support that is required as the backboard of the urethra for urinary continence.[26]
- The design of the TVT is universally accepted by the large academic bodies: ACOG, AUGS, AUA, EUA, ICS, IUGA, NICE and SUFU.[27]
- The utility of the TVT has been demonstrated in its ease of use, low morbidity, reproducibility, adaptability and efficacy.[28]
- The mesh used in the TVT is state of the art in design. It is macroporous (>75 microns) and monofilament, and the macroporosity for an only 1.1-cm-wide strip of mesh promotes mechanical anchorage with neovascularization and collagen formation. . . .[29]
- The design of the sheaths that cover the TVT mesh during implantation allows for smooth placement.[30]
- The design of the TVT optimizes safety. . . .[31]
- The design of the TVT places the mesh under the midurethra via the small proximal anterior wall incision.[32]
- The macroporous mesh is state of the art, being >75 microns and monofilament.[33]
- In addition, without the protective sheaths, there is a risk of too much stretching of the mesh, leading to suboptimal efficacy and/or too much tension.[34]
- The design factors have shown it to be a very reasonable procedure and as the standard of care for which pelvic surgeons expect.[35]

Each of these opinions specifically relates to design issues of the TVT mesh. Defendants even argue a point, i.e., Dr. Irwin's opinions about acceptance by certain organizations, this Court determined Dr. Austin was not qualified to provide in *Wise*.[36]

[25] Ex. B (Doc. No. 2006-2) at p. 25.
[26] Ex. B (Doc. No. 2006-2) at p. 27.
[27] Ex. B (Doc. No. 2006-2) at p. 40.
[28] Ex. B (Doc. No. 2006-2) at p. 41.
[29] Ex. B (Doc. No. 2006-2) at p. 42.
[30] Ex. B (Doc. No. 2006-2) at p. 43.
[31] Ex. B (Doc. No. 2006-2) at p. 45.
[32] Ex. B (Doc. No. 2006-2) at p. 46.
[33] Ex. B (Doc. No. 2006-2) at p. 46.
[34] Ex. B (Doc. No. 2006-2) at p. 49.
[35] Ex. B (Doc. No. 2006-2) at p. 51.
[36] *Wise*, 2015 WL. 570070 at *4.

Dr. Irwin's design opinions should be excluded because she is not qualified to testify about design issues related to the TVT mesh.

III. Dr. Irwin's Fraying Opinions are not Reliable

Defendants mischaracterize Dr. Irwin's opinions concerning mesh fraying and particle loss to whether these inherent conditions of the mechanically cut mesh have been shown to cause pain in women. First, Dr. Irwin's opinions concerning mesh fraying and particle loss are more extensive portrayed by Defendants. Dr. Irwin opines that "fraying and loss of particles leading to pain" "has not been shown to occur." Defendants' internal documents demonstrate the unreliability of this opinion. Dr. Irwin was not aware that Defendants have known for years that mechanically cut mesh can fray and lose particles during the implant process. In fact, Defendants have known since 1998 that mesh particles can migrate causing pelvic pain and dyspareunia.[37] She was not aware that fraying of the mesh was "inherent in the design and construction of the product" and the very act of removing the sheaths could cause fraying and particle loss.[38] Dr. Irwin was not aware that fraying and particle loss could cause degradation of the structure of the mesh.[39]

Dr. Irwin, unlike Defendants, after being confronted with these facts about fraying, particle loss and degradation of the mesh, recognized the unreliability of her opinions and conceded that "I guess I'd like to read a little more to make my opinions on this."[40]

Dr. Irwin's opinions concerning mesh fraying and particle loss are not reliable and are due to be excluded.

[37] Ex. C (Doc. No. 2006-3) at 80:19 – 82:16.
[38] Ex. C (Doc. No. 2006-3) at 83:14 – 21, 86:10 – 88:3.
[39] Ex. C (Doc. No. 2006-3) at 88:8 – 89:24.
[40] Ex. C (Doc. No. 2006-3) at 89:8-10.

IV. Dr. Irwin's "State of the Art" Opinions Constitute a Legal Conclusion

Defendants assert that Plaintiffs' challenge to Dr. Irwin's "state of the art" opinions is not a *Daubert* issue. Defendants further assert that this opinion is a matter for a motion *in limine*. Defendants ignore the fact that this Court has previously excluded opinions that constitute legal conclusions in the context of a *Daubert* motion in *Wise*.[41]

Moreover, such evidence is not admissible under Texas law on a strict liability case based on defective design but may be admissible on a failure to warn claim to show "under the technological capabilities existing at the time the product was marketed, it was unfeasible to include a warning on the product: either that a warning could not be included on the product, or that including one would make the product less useful to society."[42] Dr. Irwin's "state of the art" opinions address the design of the TVT mesh instead of whether warnings could be included or would have made the product less useful.

Defendants' reliance on *Boatland of Houston, Inc.*[43] is misplaced. First, in *Boatland of Houston, Inc.*, the Court recognized "state of the art" is not admissible in a strict liability claim under Texas law.[44] The Court noted that "evidence" of state of the art was admissible to show feasibility of a safer alternative but not to show that "a custom existed or to infer the defendant's compliance therewith."[45] Second, the Court explained further that "feasibility and effectiveness of a safer design and other factors such as utility and risk," are admissible on a negligent design claim.[46] The Court approved evidence demonstrating that kill switches were not used at the time

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[41] *Wise*, 2015 WL. 570070 at *4 (citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)("[O]pinion testimony that state a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible").
[42] *Carter v. Johns-Manville Sales Corp.*, 557 F. Supp. 1317, 1320-21 (E.D. Tx. 1983).
[43] *Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743 (Tex. 1980).
[44] *Boatland of Houston, Inc.*, 609 S.W.2d at 749.
[45] *Id.*
[46] *Id.*

of manufacture "due to limitations imposed by the state of the art."[47] Finally, the Court noted that a different question would exist if the state of the art was not disputed and the defendant "attempted to avoid liability by offering proof that [the product] complied with industry custom."[48]

Boatland of Houston, Inc. did not hold that an expert witness can testify that a product met the "state of the art" at that time. Instead, the Court held that evidence of whether a safer alternative design existed could be admissible provided the evidence was not offered to show that the Defendant complied with industry custom. In this case, Dr. Irwin's state of the art opinions are not related to the feasibility and/or effectiveness of any safer alternatives. Instead, Dr. Irwin's state of the art opinions are offered to show that Defendants complied with industry custom.

Dr. Irwin's state of the art opinions should be excluded because they constitute a legal conclusion and are not admissible under Texas law for the purposes offered.

CONCLUSION

Dr. Irwin may be qualified to provide specific causation opinions but she is not qualified to provide general causation opinions relating to the design of the TVT mesh product. Accordingly, her design opinions should be excluded. Her opinions concerning state of the art constitute a legal standard/conclusion and should be excluded. Her opinions concerning fraying issues related to mechanically cut mesh are unreliable and should be excluded.

[47] *Id.*
[48] *Id.*

This 16th day of May, 2016.

By: /s/ P. Leigh O'Dell
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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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